

REMARKS

For the Examiner's convenience Applicants will now address stated issued and grounds for rejection of the pending claims under the appropriate subheadings.

Claim Amendments

Claims 14 and 15 are newly added and recite that the polymer of the tablet of Claim 2 and the capsule of Claim 8 is water-insoluble. Support for newly added Claims 14 and 15 can be found at page 7, lines 23-24 of the Specification.

Rejection of Claims 2-3 and 8-13 Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 2-3 and 8-13 under 35 U.S.C. § 103(a) as being unpatentable over Keim (U.S. Patent No. 3,700,623) in view of McTaggart (U.S. Patent No. 5,462,730). In particular, the Examiner stated that although Keim does not teach that the described resins can be used in a pharmaceutical composition, one of skill in the art would recognize the resins as suitable for a pharmaceutical composition because McTaggart demonstrates that polyallylamine polymers can be formulated as such. Applicants disagree with the Examiner's assertions.

Applicants' claims are directed to a pharmaceutical composition comprising a unit dosage form of a polydiallylamine homopolymer, which is free of alkylated amine monomers, and a pharmaceutically acceptable carrier. Each of the two independent claims specify the structure of the unit dosage form (i.e., Claim 2 specifies a tablet and Claim 8 specifies a capsule). Newly added claims 14 and 15 recite that the polymer of the pharmaceutical composition is water-insoluble.

Keim teaches water soluble resins that are used as wet strength agents for paper and that also provide dry strength to paper. At Col 3. lines 63-75, Keim teaches that the aqueous resins are applied to the paper by tub application or by spraying of an aqueous resin solution having a solids content of 15% or less. Alternatively, this aqueous solution of resin can be added to an aqueous suspension of paper stock before paper sheet formation. There is no teaching or suggestion in Keim that the water soluble resin materials used to provide a paper with superior wet and dry strengths (e.g., wrapping paper), be used to prepare a pharmaceutical composition in

a solid unit dosage form.

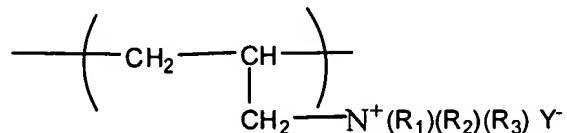
More specifically, the aqueous resin solution of Keim would not motivate one of ordinary skill in the art to prepare a pharmaceutical composition in the unit dosage form of a tablet or a capsule. In fact, preparation of a solid unit dosage form would be contrary to the teachings of Keim, which require an aqueous resin solution to strengthen paper. In other words, one of ordinary skill in the art would not be motivated to substitute a capsule or tablet for the aqueous resin solution of Keim, because such a form would destroy the ability to apply the resin to paper, because one cannot spray a tablet or capsule onto paper or dip paper in a tablet. Furthermore, the use of the resin prior to paper formation requires the addition of the aqueous resin solution, not a tablet or capsule, to the paper stock suspension. Finally, newly added claims 14 and 15, which recite that the polymer is water-insoluble, are even more distinct from the teachings of Keim, which require that the resin is water-soluble.

The Examiner relies on McTaggart to cure the deficiencies of Keim. Applicants submit that the teachings of McTaggart do not cure the deficiencies of Keim because:

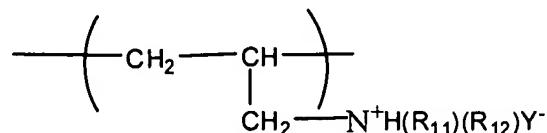
- the polymers of McTaggart are structurally diverse from the polymers of Keim; and
- the polymers of McTaggart are water-insoluble, while Keim's polymers are water-soluble.

Structural Diversity

The polymers of McTaggart are insoluble swellable polymeric allylammonium derivatives having a quaternary propylammonium monomeric unit of the following formula:

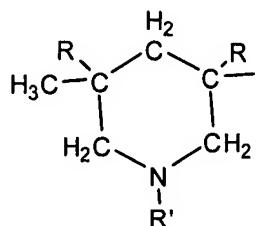


a crosslinking unit and a propylamine unit of the formula:



where the R groups can be alkyl or phenyl moieties.

On the contrary, the polydiallylamine polymers of Keim having the following cyclic monomer unit (McTaggart's monomer unit is non-cyclic) and no quaternary ammonium (required by McTaggart):



where R is hydrogen or alkyl and R' is hydrogen, alkyl or substituted alkyl.

Based on the significant structural diversity in the monomers unit of Keim and McTaggart, one of ordinary skill in the art would not be motivated to substitute the polydiallylamine of Keim for the propylammonium-containing polymer of McTaggart. More specifically, substitution of the propylammonium-containing polymer of McTaggart with the polydiallylamine polymer of Keim is not a routine substitution of one amine polymer for another to obtain predictable results, because of the significant structural diversity between the described polymers. Furthermore, McTaggart provides no suggestion or teaching that polymers other than the non-cyclic, hydrophobic propylammonium-containing polymers are suitable for use in the described pharmaceutical compositions. As such, one would not be motivated to use other amine polymers in the pharmaceutical compositions of McTaggart, and certainly not the structurally diverse amine polymers of Keim.

Water Solubility

Keim teaches that the described polydiallylamine polymers, used in paper processing, are water-soluble. On the contrary the polymers of McTaggart are water insoluble. Based on the difference in this important physical characteristic of the polymers, one of ordinary skill in the art would not be motivated to substitute the polydiallylamine polymer of Keim for the propylammonium-containing polymer of McTaggart, with any reasonable expectation of obtaining a solid pharmaceutical composition as claimed by Applicants.

In view of the above, Applicants' claims meet the requirement of 35 U.S.C. 103(a) and are patentable over the teachings of Keim either alone or in combination with McTaggart. Reconsideration and withdrawal of the rejection are respectfully requested.

Finally, the Examiner's reference to *In re Spada* on page 4 of the Office Action is not understood. The pending rejection is based on obviousness of Applicants' claimed invention, not anticipation as the application of *In re Spada* would suggest. In any event, the aqueous solution of water soluble resin described in Keim is not identical to the unit dosage form (i.e., tablet or capsule) of Applicants' claimed invention, particularly the composition of newly added Claims 14 and 15 which recite that the polymer is water-insoluble.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Susan M. Abelleira
Susan M. Abelleira
Registration No. 42,252
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Date: *February 08, 2008*